

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark one)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2021

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.
Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

58-2301143

(IRS Employer
Identification Number)

**210 Main Street West
Baudette, Minnesota 56623**

(Address of principal executive offices)

(218) 634-3500

(Registrant's telephone number including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	ANIP	Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of July 30, 2021 there were 12,751,512 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

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ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended June 30, 2021

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such statements include, but are not limited to, the announcement and pendency of the acquisition of Novitium Pharma LLC ("Novitium"), statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, expected pre-launch charges for Cortrophin, impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including those discussed in the "Risk Factors" section in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2021, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

- the ability of the parties to complete the announced acquisition of Novitium or any delay in the completion of the acquisition;
- risks that we may face with respect to importing raw materials;
- delays or failure in obtaining approvals by the FDA of the products we sell;
- changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls;
- the ability of our manufacturing partners to meet our product demands and timelines;
- our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply;
- acceptance of our products at levels that will allow us to achieve profitability;
- our ability to develop, license or acquire, and commercialize new products;
- the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become, a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;

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- *our ability to maintain the services of our key executives and other personnel; and*
- *general business and economic conditions and the effects and duration of outbreaks of public health emergencies, such as COVID-19.*

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2020, including the factors described in “Item 1A. Risk Factors.” Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

NOTE REGARDING TRADEMARKS

Apexicon®, Cortenema®, Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, Vancocin®, and VEREGEN® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. OXISTAT® is the property of Fougera Pharmaceuticals Inc. and licensed to ANI Pharmaceuticals, Inc. for U.S. sales of OXISTAT® Lotion. Pandel® is property of Taisho Pharmaceutical Co, Ltd. and licensed to ANI Pharmaceuticals for U.S. sales of Pandel® creme.

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Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	<i>June 30, 2021</i>	<i>December 31, 2020</i>
Assets		
Current Assets		
Cash and cash equivalents	\$ 24,261	\$ 7,864
Accounts receivable, net of \$92,130 and \$100,328 of adjustments for chargebacks and other allowances at June 30, 2021 and December 31, 2020, respectively	92,648	95,793
Inventories, net	67,634	60,803
Prepaid income taxes	2,375	—
Prepaid expenses and other current assets	4,881	5,861
Total Current Assets	<u>191,799</u>	<u>170,321</u>
Property and equipment	60,336	58,797
Accumulated depreciation	(20,002)	(17,528)
Property and equipment, net	40,334	41,269
Restricted cash	5,001	5,003
Deferred tax assets, net of deferred tax liabilities and valuation allowance	58,526	51,704
Intangible assets, net	180,199	188,511
Goodwill	3,580	3,580
Other non-current assets	720	802
Total Assets	<u>\$ 480,159</u>	<u>\$ 461,190</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	\$ 15,182	\$ 13,243
Accounts payable	12,977	11,261
Accrued expenses and other	11,582	2,456
Accrued royalties	4,688	6,407
Accrued compensation and related expenses	4,319	6,231
Current income taxes payable, net	—	3,906
Accrued government rebates	8,740	7,826
Returned goods reserve	31,904	27,155
Deferred revenue	62	80
Total Current Liabilities	<u>89,454</u>	<u>78,565</u>
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	189,525	172,443
Derivatives and other non-current liabilities	9,263	14,482
Total Liabilities	<u>\$ 288,242</u>	<u>\$ 265,490</u>
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock: \$0.0001 par value, 33,333,334 shares authorized; 12,825,658 shares issued and 12,745,573 outstanding at June 30, 2021; 12,429,916 shares issued and 12,354,398 shares outstanding at December 31, 2020	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Treasury stock, 80,085 shares of common stock, at cost, at June 30, 2021 and 75,518 shares of common stock, at cost, at December 31, 2020	(3,062)	(2,246)
Additional paid-in capital	219,403	214,354
Accumulated deficit	(18,992)	(4,972)
Accumulated other comprehensive loss, net of tax	(5,433)	(11,437)
Total Stockholders' Equity	<u>191,917</u>	<u>195,700</u>
Total Liabilities and Stockholders' Equity	<u>\$ 480,159</u>	<u>\$ 461,190</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	<i>Three Months Ended June 30,</i> <i>2021</i>	<i>2020</i>	<i>Six Months Ended June 30,</i> <i>2021</i>	<i>2020</i>
Net Revenues	\$ 48,625	\$ 48,470	\$ 103,146	\$ 98,244
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	22,314	20,695	42,299	42,499
Research and development	2,805	3,035	5,773	9,379
Selling, general, and administrative	18,820	21,213	36,407	34,896
Depreciation and amortization	11,324	11,198	22,222	22,381
Legal settlement expense	8,400	—	8,400	—
Cortrophin pre-launch charges	515	3,636	553	8,238
Total Operating Expenses	<u>64,178</u>	<u>59,777</u>	<u>115,654</u>	<u>117,393</u>
Operating Loss	(15,553)	(11,307)	(12,508)	(19,149)
Other Expense, net				
Interest expense, net	(2,531)	(2,356)	(4,985)	(4,388)
Other expense, net	(67)	(116)	(582)	(106)
Loss Before Benefit for Income Taxes	<u>(18,151)</u>	<u>(13,779)</u>	<u>(18,075)</u>	<u>(23,643)</u>
Benefit for income taxes	<u>4,045</u>	<u>1,443</u>	<u>4,055</u>	<u>4,296</u>
Net Loss	<u><u>\$ (14,106)</u></u>	<u><u>\$ (12,336)</u></u>	<u><u>\$ (14,020)</u></u>	<u><u>\$ (19,347)</u></u>
Basic and Diluted Loss Per Share:				
Basic Loss Per Share	\$ (1.17)	\$ (1.03)	\$ (1.16)	\$ (1.62)
Diluted Loss Per Share	\$ (1.17)	\$ (1.03)	\$ (1.16)	\$ (1.62)
Basic Weighted-Average Shares Outstanding	12,085	11,967	12,045	11,935
Diluted Weighted-Average Shares Outstanding	<u>12,085</u>	<u>11,967</u>	<u>12,045</u>	<u>11,935</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Comprehensive Income/(Loss)
(in thousands)
(unaudited)

	<i>Three Months Ended June 30,</i> <i>2021</i>	<i>2020</i>	<i>Six Months Ended June 30,</i> <i>2021</i>	<i>2020</i>
Net loss	\$ (14,106)	\$ (12,336)	\$ (14,020)	\$ (19,347)
Other comprehensive (loss)/income, net of tax:				
(Losses)/gains on interest rate swap	(401)	(2,360)	6,004	(9,178)
Total other comprehensive (loss)/income, net of tax	<u>(401)</u>	<u>(2,360)</u>	<u>6,004</u>	<u>(9,178)</u>
Total comprehensive loss, net of tax	<u><u>\$ (14,507)</u></u>	<u><u>\$ (14,696)</u></u>	<u><u>\$ (8,016)</u></u>	<u><u>\$ (28,525)</u></u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Three Months Ended June 30, 2021 and 2020
(in thousands)
(unaudited)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive Loss, Net of Tax	Retained Earnings/ (Accumulated Deficit)	Total
Balance, March 31, 2020	\$ 1	12,112	\$ —	\$ 203,505	28	\$ (1,211)	\$ (11,689)	\$ 10,565	\$ 201,171
Stock-based Compensation Expense	—	—	—	5,736	—	—	—	—	5,736
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	30	(1,035)	—	—	(1,035)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	7	—	168	—	—	—	—	168
Issuance of Restricted Stock Awards	—	261	—	—	—	—	—	—	—
Losses on Interest Rate Swap	—	—	—	—	—	—	(2,360)	—	(2,360)
Net Loss	—	—	—	—	—	—	—	(12,336)	(12,336)
Balance, June 30, 2020	\$ 1	12,380	\$ —	\$ 209,409	58	\$ (2,246)	\$ (14,049)	\$ (1,771)	\$ 191,344
Balance, March 31, 2021	\$ 1	12,830	\$ —	\$ 216,223	86	\$ (2,594)	\$ (5,032)	\$ (4,886)	\$ 203,712
Stock-based Compensation Expense	—	—	—	2,844	—	—	—	—	2,844
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	15	(468)	—	—	(468)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	12	—	337	—	—	—	—	337
Issuance of Restricted Stock Awards	—	19	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	(35)	—	(1)	(21)	—	—	—	(1)
Losses on Interest Rate Swap	—	—	—	—	—	—	(401)	—	(401)
Net Loss	—	—	—	—	—	—	—	(14,106)	(14,106)
Balance, June 30, 2021	\$ 1	12,826	\$ —	\$ 219,403	80	\$ (3,062)	\$ (5,433)	\$ (18,992)	\$ 191,917

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Six Months Ended June 30, 2021 and 2020
(in thousands)
(unaudited)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive Gain/(Loss), Net of Tax	Retained Earnings/ (Accumulated Deficit)	Total
Balance, December 31, 2019	\$ 1	12,105	\$ —	\$ 200,800	15	\$ (723)	\$ (4,871)	\$ 17,584	\$ 212,791
Cumulative Effect of Change in Accounting Principle, Net of Tax	—	—	—	—	—	—	—	(8)	(8)
Stock-based Compensation Expense	—	—	—	8,160	—	—	—	—	8,160
Treasury Stock Purchases for Restricted Stock	—	—	—	—	—	—	—	—	—
Vests	—	—	—	—	43	(1,523)	—	—	(1,523)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	14	—	449	—	—	—	—	449
Issuance of Restricted Stock	—	261	—	—	—	—	—	—	—
Awards	—	—	—	—	—	—	—	—	—
Losses on Interest Rate Swap	—	—	—	—	—	—	(9,178)	—	(9,178)
Net Loss	—	—	—	—	—	—	—	(19,347)	(19,347)
Balance, June 30, 2020	\$ 1	12,380	\$ —	\$ 209,409	58	\$ (2,246)	\$ (14,049)	\$ (1,771)	\$ 191,344
Balance, December 31, 2020	\$ 1	12,430	\$ —	\$ 214,354	76	\$ (2,246)	\$ (11,437)	\$ (4,972)	\$ 195,700
Stock-based Compensation Expense	—	—	—	4,713	—	—	—	—	4,713
Treasury Stock Purchases for Restricted Stock	—	—	—	—	25	(816)	—	—	(816)
Vests	—	—	—	—	—	—	—	—	—
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	12	—	337	—	—	—	—	337
Issuance of Restricted Stock	—	457	—	—	—	—	—	—	—
Awards	—	(73)	—	(1)	(21)	—	—	—	(1)
Restricted Stock Awards Forfeitures	—	—	—	—	—	—	—	—	—
Gains on Interest Rate Swap	—	—	—	—	—	—	6,004	—	6,004
Net Loss	—	—	—	—	—	—	—	(14,020)	(14,020)
Balance, June 30, 2021	\$ 1	12,826	\$ —	\$ 219,403	80	\$ (3,062)	\$ (5,433)	\$ (18,992)	\$ 191,917

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	<i>Six Months Ended June 30,</i> <i>2021</i>		<i>2020</i>	
Cash Flows From Operating Activities				
Net loss	\$ (14,020)		\$ (19,347)	
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:				
Stock-based compensation	4,713		8,160	
Deferred taxes	(6,676)		(14,100)	
Depreciation and amortization	22,222		22,381	
Acquired in-process research and development ("IPR&D")	—		3,753	
Non-cash interest	1,141		705	
Changes in operating assets and liabilities, net of acquisitions:				
Accounts receivable, net	3,145		(1,033)	
Inventories, net	2,823		4,055	
Prepaid expenses and other current assets	1,202		878	
Accounts payable	1,688		665	
Accrued royalties	(1,719)		920	
Current income taxes payable, net	(6,281)		9,362	
Accrued government rebates	914		816	
Returned goods reserve	4,754		3,408	
Accrued expenses, accrued compensation, and other	7,003		1,967	
Net Cash and Cash Equivalents Provided by Operating Activities	20,909		22,590	
Cash Flows From Investing Activities				
Acquisition of product rights, IPR&D, and other related assets	(21,057)		(58,130)	
Acquisition of property and equipment, net	(1,630)		(2,264)	
Net Cash and Cash Equivalents Used in Investing Activities	(22,687)		(60,394)	
Cash Flows From Financing Activities				
Payments on Term Loan and Delayed Draw Term Loan agreements	(5,206)		(3,279)	
Borrowings under Revolver agreement	24,000		15,000	
Payments on Revolver agreement	—		(7,500)	
Proceeds from stock option exercises and ESPP purchases	336		449	
Payments of debt issuance costs	(141)		—	
Treasury stock purchases for restricted stock vests	(816)		(1,523)	
Net Cash and Cash Equivalents Provided by Financing Activities	18,173		3,147	
Net Change in Cash and Cash Equivalents	16,395		(34,657)	
Cash and cash equivalents, beginning of period	12,867		67,361	
Cash and cash equivalents, end of period	<u>\$ 29,262</u>		<u>\$ 32,704</u>	
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period				
Cash and cash equivalents	\$ 7,864		\$ 62,332	
Restricted cash	5,003		5,029	
Cash, cash equivalents, and restricted cash, beginning of period	<u>\$ 12,867</u>		<u>\$ 67,361</u>	
Reconciliation of cash, cash equivalents, and restricted cash, end of period				
Cash and cash equivalents	\$ 24,261		\$ 27,702	
Restricted cash	5,001		5,002	
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 29,262</u>		<u>\$ 32,704</u>	
Supplemental disclosure for cash flow information:				
Cash paid for interest, net of amounts capitalized	\$ 3,953		\$ 3,541	
Cash paid for income taxes	\$ 8,360		\$ 523	
Supplemental non-cash investing and financing activities:				
Debt issuance costs in accrued expenses	\$ 81		\$ —	
Property and equipment purchased and included in accounts payable	<u>\$ 119</u>		<u>\$ 161</u>	

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, “ANI,” the “Company,” “we,” “us,” or “our”) is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities, including controlled substances, oncology products (anti-cancer), hormones and steroids, and complex formulations. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, comprehensive income, and cash flows. The consolidated balance sheet at December 31, 2020 has been derived from audited financial statements as of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the U.S. Securities and Exchange Commission (the “SEC”). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Principles of Consolidation

The unaudited interim condensed consolidated financial statements include the accounts of ANI Pharmaceuticals, Inc. and its subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

Foreign Currency

We have a subsidiary located in Canada. The subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The results of any non-U.S. dollar transactions are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain or loss on transactions denominated in foreign currencies was immaterial for the three and six months ended June 30, 2021 and 2020. Unless otherwise noted, all references to “\$” or “dollar” refer to the U.S. dollar.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited interim condensed consolidated financial statements, estimates are

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

used for, but not limited to, stock-based compensation, revenue recognition, allowance for credit losses, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, income tax provision or benefit, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

We are subject to risks and uncertainties as a result of the novel coronavirus (“COVID-19”) pandemic. We are unable to predict the impact that the COVID-19 pandemic will continue have on our future business, financial condition, and results of operations due to numerous uncertainties. These uncertainties include the occurrence of recurring outbreaks and their severity and the duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. We remain unable to predict the future impact on our estimates and assumptions. There was not a material impact to these estimates or assumptions in our consolidated financial statements as of and for the three and six months ended June 30, 2021 and 2020. Actual results could differ from those estimates, which may change our estimates in future periods. We continue to closely monitor the impact of the COVID-19 pandemic on our business.

Geographic Information

Based on the distinct nature of our operations, our internal management structure, and the financial information that is evaluated regularly by our Chief Operating Decision Maker, we determined that we operate in one reportable segment. Our operations are located in the United States and Canada. The majority of the assets of the Company are located in the United States.

The following table depicts the Company’s revenue by geographic operations during the following periods:

(in thousands) Location of Operations	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
United States	\$ 47,580	\$ 46,277	\$ 100,907	\$ 94,508
Canada	1,045	2,193	2,239	3,736
Total Revenue	\$ 48,625	\$ 48,470	\$ 103,146	\$ 98,244

The following table depicts the Company’s property and equipment, net according to geographic location as of:

(in thousands)	June 30, 2021		December 31, 2020	
	United States	\$ 26,252	\$ 26,960	\$ 14,309
Canada		14,082		
Total property and equipment, net		\$ 40,334		\$ 41,269

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

We have evaluated all issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our condensed consolidated statements of operations, comprehensive income, balance sheets, or cash flows.

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Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board (“FASB”) issued guidance simplifying the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts on an entity’s own equity. The new standard removes the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It also removes certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and simplifies the diluted earnings per share calculation for convertible instruments. We early adopted this guidance as of January 1, 2021. The adoption of this guidance did not have a material impact on our consolidated financial statements but will impact how we account for newly issued convertible instruments in future periods.

In November 2019, the FASB issued guidance simplifying the accounting for income taxes by removing the following exceptions: 1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, 2) exception requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment, 3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and 4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also simplify accounting for income taxes by doing the following: 1) requiring that an entity recognize a franchise tax or similar tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, 2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, 3) specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements, 4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and 5) making minor Codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method. Most of the provisions of this guidance were to be adopted on a prospective basis. Items 2) and 3) of the “removal” provisions were to be adopted on either a full or modified retrospective basis and item 4) of the “simplifying” provisions was to be adopted on a full retrospective basis. The guidance was effective for reporting periods beginning after December 15, 2020, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2021. The adoption of this guidance did not have a material impact on our consolidated financial statements.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

We recognize revenue using the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

We derive our revenues primarily from sales of generic and branded pharmaceutical products. Revenue is recognized when our obligations under the terms of our contracts with customers are satisfied, which generally occurs when control of the products we sell is transferred to the customer. We estimate variable consideration after considering applicable information that is reasonably available. We generally do not have incremental costs to

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obtain contracts that would otherwise not have been incurred. We do not adjust revenue for the promised amount of consideration for the effects of a significant financing component because our customers generally pay us within 100 days.

All revenue recognized in the accompanying unaudited interim condensed consolidated statements of operations is considered to be revenue from contracts with customers. The following table depicts the disaggregation of revenue:

Products and Services (in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Sales of generic pharmaceutical products	\$ 34,199	\$ 33,400	\$ 66,812	\$ 70,895
Sales of branded pharmaceutical products	11,038	10,633	18,555	19,790
Sales of contract manufactured products	2,322	2,900	4,895	4,874
Royalties from licensing agreements	—	491	11,210	781
Product development services	97	885	255	1,462
Other	969	161	1,419	442
Total net revenues	<u>\$ 48,625</u>	<u>\$ 48,470</u>	<u>\$ 103,146</u>	<u>\$ 98,244</u>

Timing of Revenue Recognition (in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Performance obligations transferred at a point in time	\$ 48,528	\$ 47,585	\$ 102,891	\$ 96,782
Performance obligations transferred over time	97	885	255	1,462
Total	<u>\$ 48,625</u>	<u>\$ 48,470</u>	<u>\$ 103,146</u>	<u>\$ 98,244</u>

In the three and six months ended June 30, 2021 and 2020, we did not incur, and therefore did not defer, any material incremental costs to fulfill contracts. We recognized an increase of \$10.3 million to net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2021, consisting primarily of a final \$11.2 million royalty revenue related to the Kite license agreement pursuant to the Tripartite Agreement as described herein in *Royalties from Licensing Agreements*, which was partially offset by a decrease related to revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We recognized a decrease of \$5.7 million of net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2020, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We provide technical transfer services to customers, for which services are transferred over time. As of June 30, 2021 and December 31, 2020, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. We had \$0.1 million of deferred revenue at June 30, 2021 and December 31, 2020. For the three and six months ended June 30, 2021, we recognized less than \$0.1 million of revenue that was included in deferred revenue as of December 31, 2020. For the three and six months ended June 30, 2020, we recognized \$0.3 million and \$0.2 million, respectively, of revenue that was included in deferred revenue as of December 31, 2019.

Revenue from Sales of Generic and Branded Pharmaceutical Products

Product sales consists of sales of our generic and brand pharmaceutical products. Our sole performance obligation in our contracts is to provide pharmaceutical products to customers. Our products are sold at pre-determined standalone selling prices and our performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is generally transferred to the customer upon delivery of the product to the

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customer, as our pharmaceutical products are generally sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery. Payment terms for these sales are generally less than 100 days.

Sales of our pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment. A comprehensive discussion of variable consideration is included in Part II, Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2020.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the six months ended June 30, 2021 and 2020, respectively:

(in thousands)	Accruals for Chargebacks, Returns, and Other Allowances				
	Government	Administrative	Prompt	Fees and Other	Payment
	Chargebacks	Rebates	Returns	Rebates	Discounts
Balance at December 31, 2019 (1)	\$ 49,882	\$ 8,901	\$ 16,595	\$ 8,281	\$ 2,549
Accruals/Adjustments	181,986	7,519	14,103	17,392	6,551
Credits Taken Against Reserve	(169,345)	(6,703)	(10,695)	(17,161)	(6,277)
Balance at June 30, 2020 (1)	<u>\$ 62,523</u>	<u>\$ 9,717</u>	<u>\$ 20,003</u>	<u>\$ 8,512</u>	<u>\$ 2,823</u>
Balance at December 31, 2020 (1)	\$ 88,746	\$ 7,826	\$ 27,155	\$ 8,906	\$ 3,839
Accruals/Adjustments	214,125	12,980	21,058	32,207	13,315
Credits Taken Against Reserve	(220,776)	(12,066)	(16,309)	(33,071)	(13,682)
Balance at June 30, 2021 (1)	<u>\$ 82,095</u>	<u>\$ 8,740</u>	<u>\$ 31,904</u>	<u>\$ 8,042</u>	<u>\$ 3,472</u>

- (1) Chargebacks are included as an offset to accounts receivable in the unaudited condensed consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included as an offset to accounts receivable or as accrued expenses and other in the unaudited condensed consolidated balance sheets. Returns are included in returned goods reserve in the unaudited condensed consolidated balance sheets. Government Rebates are included in accrued government rebates in the unaudited condensed consolidated balance sheets.

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which we manufacture a pharmaceutical product on behalf of a third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our contract manufactured pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally fewer than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products.

As of June 30, 2021, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was \$3.6 million, which consists of firm orders for contract manufactured products. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within six months.

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Royalties from Licensing Agreements

From time to time, we enter into transition agreements with the sellers of products we acquire, under which we license to the seller the right to sell the acquired products. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. Upon full transition of the products and upon launching the products under our own labels, we recognize revenue for the products as sales of generic or branded pharmaceutical products, as described above. From time to time, we enter into supply and distribution agreements with contract manufacturing customers, under which we license to the contract manufacturing customer the right to sell our products, and we are entitled to a royalty on sales made by the contract manufacturing customer under these arrangements. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the contract manufacturing customers.

Pursuant to a 2012 Tripartite Agreement (the “Tripartite Agreement”) between the Company, The Regents of the University of California (“The Regents”), and Cabaret Biotech Ltd., an Israeli corporation (“Cabaret”) (as assignee of Dr. Zelig Eshhar’s rights under the Tripartite Agreement), and subsequent amendments thereto and assignments thereof, we were entitled to receive a percentage of the milestone and sales royalty payments paid to Cabaret by Kite Pharma, Inc. (“Kite”), a subsidiary of Gilead Sciences, Inc., under a license agreement. Under such license agreement, Kite licensed from Dr. Eshhar and Cabaret the patent rights covered by the Tripartite Agreement and agreed to make certain payments to Cabaret based on, among other things, Kite’s sales of Yescarta®. Under the Tripartite Agreement, portions of these payments were to be distributed to The Regents and to us.

Historically, we recorded royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash was received directly from Cabaret once a year. The agreements governing this royalty were subject to multiple actions in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, ANI and Cabaret. In the first quarter of 2021, we became aware that the litigation between Cabaret and Kite was dismissed. In April 2021, Cabaret and the Company settled all amounts due for amounts actually received by Cabaret or Eshhar for the licensing or use of the patent rights governed by the Kite license agreement. As a result, we recognized \$11.2 million as royalties from licensing agreements in our net revenues during the three month period ended March 31, 2021. In addition, we agreed to reimburse Cabaret \$0.4 million, which has been recorded as other expense, net in the accompanying unaudited interim condensed consolidated statement of operations, related to certain legal expenditures incurred. We received final payment from Cabaret in May 2021. Based upon the events that led to the dismissal of the litigation between Cabaret and Kite, the Company does not expect to receive any future royalty income related to the Kite license agreement. In conjunction with payment of amounts due to us, all outstanding litigation between the Company and Cabaret were dismissed.

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These services primarily relate to the technical transfer of product development to our facility in Oakville, Ontario. The duration of these technical transfer projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. As of June 30, 2021, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was \$0.6 million. We expect to satisfy these performance obligations within the next six months.

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Credit Concentration

Our customers are primarily wholesale distributors, chain drug stores, group purchasing organizations, and pharmaceutical companies.

During the three and six months ended June 30, 2021 and 2020 we had three customers that accounted for 10% or more of net revenues. As of June 30, 2021, accounts receivable from these customers totaled 86% of accounts receivable, net. Additionally, 11% of our net revenue during the six months ended June 30, 2021 relates to royalty revenue from one customer pursuant to the Tripartite Agreement.

The three customers represent the total percentage of net revenues as follows:

	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Customer 1	34 %	33 %	29 %	32 %
Customer 2	26 %	22 %	22 %	23 %
Customer 3	14 %	19 %	14 %	19 %

3. PENDING BUSINESS COMBINATION

On March 8, 2021, we entered into a definitive agreement to acquire Novitium Pharma LLC (“Novitium”), a privately held New Jersey-based pharmaceutical company with development, manufacturing, and commercial capabilities (the “Acquisition”). The closing of the Acquisition will occur (a) within five business days after all of the conditions to the closing set forth in the merger agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by us and Novitium, subject to the completion of a minimum period. The closing is subject to the satisfaction of customary closing conditions and necessary regulatory approvals.

Consideration will consist of a combination of (i) an estimated cash amount of \$89.5 million, subject to various adjustments and expected to be financed by a \$25.0 million private placement of preferred stock (the “PIPE Investment”) and by new debt financing, both described below, (ii) an aggregate of 2,466,667 shares of ANI common stock, and (iii) up to \$46.5 million in contingent future earn-out payments.

We will finance the transaction with a new \$340.0 million Senior Secured Credit Facility (the “New Facility”), consisting of a \$300.0 million term loan and a \$40.0 million revolving credit facility, the issuance of 2,466,667 shares of ANI common stock (approximately \$74.0 million in value based on a \$30.0 stock price), and a \$25.0 million PIPE Investment by Ampersand 2020 Limited Partnership (“Ampersand”), an affiliate of Ampersand Capital Partners. At closing, we intend to use the proceeds from the New Facility to fund a portion of the Acquisition and repay all of the outstanding debt under the existing senior secured credit facility. The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI’s existing senior credit facilities. The term loan portion of the New Facility, which was successfully syndicated on May 24, 2021, represents fully committed capital and, as such, carries customary ticking fees that commence 45 days and 90 days post allocation.

Concurrently with the execution of the definitive agreement, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand (the “PIPE Investor”), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock, for a purchase price of \$1,000 per share and an aggregate purchase price of \$25.0 million PIPE Investment.

Patrick D. Walsh, Chairman of ANI’s board of directors, is an operating partner for Ampersand Capital Partners.

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The PIPE Investment and issuance of shares of ANI common stock were approved by the ANI shareholders in June 2021 at its Annual Meeting of Stockholders.

During the three and six months ended June 30, 2021, we incurred approximately \$1.7 million and \$4.6 million, respectively, in transaction costs related to this pending Acquisition, all of which were expensed and recognized as selling, general, and administrative expenses on the unaudited interim condensed consolidated statements of operations.

4. INDEBTEDNESS

Credit Facility

Our five-year Senior Secured Credit Facility (the “Credit Facility”) is comprised of a \$72.2 million term loan (the “Term Loan”), a \$118.0 million delayed draw term loan (“DDTL”), and a \$75.0 million revolving credit facility (the “Revolver”), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. The Term Loan includes a repayment schedule, pursuant to which \$6.8 million of the loan will be paid in quarterly installments during the 12 months ended June 30, 2022. As of June 30, 2021, \$6.8 million of the Term Loan is recorded as current borrowings in the consolidated balance sheets. The DDTL includes a repayment schedule, pursuant to which \$8.9 million will be paid in quarterly installments during the 12 months ended June 30, 2022. As of June 30, 2021, \$8.9 million of the DDTL is recorded as current borrowings in the consolidated balance sheets. As of June 30, 2021, there is \$31.5 million outstanding and payable on our Revolver, all of which is recorded as a long-term borrowing on the consolidated balance sheets. As of June 30, 2021, \$43.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a 1-month LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending on our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of June 30, 2021, our interest rate on outstanding borrowings was 1-month LIBOR plus 2.00% and our commitment fee rate was 0.4%.

The Credit Facility is secured by a lien on substantially all of ANI Pharmaceuticals, Inc.’s and its principal domestic subsidiary’s assets and any future domestic subsidiary guarantors’ assets. The Credit Facility is subject to customary financial and nonfinancial covenants.

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The carrying value of the current and non-current components of the Term Loan and DDTL as of June 30, 2021 and December 31, 2020 are:

(in thousands)	Current	
	June 30, 2021	December 31, 2020
Current borrowing on debt	\$ 15,617	\$ 13,691
Deferred financing costs	(435)	(448)
Current debt, net of deferred financing costs	<u>\$ 15,182</u>	<u>\$ 13,243</u>
(in thousands)	Non-Current	
	June 30, 2021	December 31, 2020
Non-current borrowing on debt	\$ 158,623	\$ 165,755
Deferred financing costs	(598)	(812)
Non-current debt, net of deferred financing costs and current component	<u>\$ 158,025</u>	<u>\$ 164,943</u>

As of June 30, 2021, we had a \$63.6 million balance on the Term Loan, \$110.6 million balance on the DDTL, and \$31.5 million balance on the Revolver. Of the \$0.6 million of deferred debt issuance costs allocated to the Revolver, \$0.4 million is included in other non-current assets in the accompanying unaudited interim condensed consolidated balance sheets and \$0.2 million is included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheets.

The contractual maturity of our Term Loan, DDTL, and Revolver is as follows for the years ending December 31:

(in thousands)	Term Loan	DDTL	Revolver
2021	\$ 4,060	\$ 4,425	\$ —
2022	5,414	8,850	—
2023	54,141	97,350	31,500
Total	<u>\$ 63,615</u>	<u>\$ 110,625</u>	<u>\$ 31,500</u>

The following table sets forth the components of total interest expense related to the Term Loan, DDTL, and Revolver recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020:

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Contractual coupon	\$ 2,386	\$ 2,206	\$ 4,690	\$ 4,099
Amortization of finance fees	176	180	352	362
Capitalized interest	(31)	(24)	(57)	(49)
	<u>\$ 2,531</u>	<u>\$ 2,362</u>	<u>\$ 4,985</u>	<u>\$ 4,412</u>

5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

At times we use derivative financial instruments to hedge our exposure to interest rate risks. All derivative financial instruments are recognized as either assets or liabilities at fair value on the consolidated balance sheet and are classified as current or non-current based on the scheduled maturity of the instrument.

When we enter into a hedge arrangement and intend to apply hedge accounting, we formally document the hedge relationship and designate the instrument for financial reporting purposes as a fair value hedge, a cash flow hedge,

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or a net investment hedge. When we determine that a derivative financial instrument qualifies as a cash flow hedge and is effective, the changes in fair value of the instrument are recorded in accumulated other comprehensive loss, net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

In December 2018, we refinanced our previous Credit Agreement and, at the same time, entered into an interest rate swap, which was considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our Term Loan. In February 2019, we entered into an interest rate swap, which was considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL. The hedges had been designated as effective cash flow hedges and qualified for hedge accounting. The interest rate swaps related to the Term Loan and DDTL had a weighted average fixed rate of 2.60% and 2.47%, respectively, with a maturity in December 2023. In April 2020, we terminated the remaining \$184.2 million notional value of these interest rate swaps and are recognizing the net loss in accumulated other comprehensive loss at the time of the termination to interest expense over the remaining terms through December 2023.

At the same time in April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under our Term Loan and DDTL. The interest rate swap matures in December 2026. As of June 30, 2021, the notional amount of the interest rate swap was \$174.2 million and decreases in line with maturities of our Term Loan and DDTL until December 2023, after which it remains static until maturity in 2026. The interest rate swap provides an effective fixed rate of 1.99% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The interest rate swap effectively provides a fixed rate of interest throughout the life of our Term Loan and DDTL. As of June 30, 2021, the fair value of the interest rate swap liability was valued at \$9.0 million and was recorded in derivatives and other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of June 30, 2021, \$5.4 million was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets.

During the three and six months ended June 30, 2021, the change in the fair value of the interest rate swap of \$1.4 million, net of \$0.1 million of tax and \$4.1 million, net of \$0.1 million of tax, was recorded in accumulated other comprehensive income, net of tax in our unaudited interim condensed consolidated statements of comprehensive income/(loss). Differences between the hedged 1-month LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Loan and DDTL based on the 1-month LIBOR rate. In the three and six months ended June 30, 2021, \$1.2 million and \$2.4 million of interest expense was recognized in relation to the interest rate swap, respectively.

6. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing net income (loss) available to common shareholders by the weighted-average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, we calculate diluted earnings (loss) per share by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, shares to be purchased under our Employee Stock Purchase Plan (“ESPP”), unvested restricted stock awards, and stock purchase warrants, using the treasury stock method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic and diluted earnings (loss) per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares, and excludes the impact of those shares from the denominator.

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Earnings (loss) per share for the three and six months ended June 30, 2021 and 2020 are calculated for basic and diluted earnings (loss) per share as follows:

(in thousands, except per share amounts)	Basic		Diluted		Basic		Diluted	
	Three Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020	2021	2020	2021	2020
Net loss	\$ (14,106)	\$ (12,336)	\$ (14,106)	\$ (12,336)	\$ (14,020)	\$ (19,347)	\$ (14,020)	\$ (19,347)
Net income allocated to restricted stock	—	—	—	—	—	—	—	—
Net loss allocated to common shares	<u>\$ (14,106)</u>	<u>\$ (12,336)</u>	<u>\$ (14,106)</u>	<u>\$ (12,336)</u>	<u>\$ (14,020)</u>	<u>\$ (19,347)</u>	<u>\$ (14,020)</u>	<u>\$ (19,347)</u>
Basic Weighted-Average Shares								
Outstanding	12,085	11,967	12,085	11,967	12,045	11,935	12,045	11,935
Dilutive effect of stock options and ESPP			—	—			—	—
Diluted Weighted-Average Shares			12,085	11,967			12,045	11,935
Outstanding			12,085	11,967			12,045	11,935
Loss per share	\$ (1.17)	\$ (1.03)	\$ (1.17)	\$ (1.03)	\$ (1.16)	\$ (1.62)	\$ (1.16)	\$ (1.62)

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, was 1.7 million and 1.0 million for the three months ended June 30, 2021 and 2020, and was 1.7 million and 1.4 million for the six months ended June 30, 2021 and 2020, respectively. For the three and six months ended June 30, 2021 and 2020, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because we recognized a net loss.

7. INVENTORIES

Inventories consist of the following as of:

	June 30, 2021	December 31, 2020
(in thousands)		
Raw materials	\$ 38,877	\$ 41,591
Packaging materials	3,347	3,194
Work-in-progress	631	886
Finished goods	30,267	20,363
	73,122	66,034
Reserve for excess/obsolete inventories	(5,488)	(5,231)
Inventories, net	<u>\$ 67,634</u>	<u>\$ 60,803</u>

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Vendor Concentration

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. During the three and six months ended June 30, 2021, no single vendor represented at least 10% of inventory purchases. During the three months ended June 30, 2020, we purchased approximately 13% of our inventory from one supplier. During the six months ended June 30, 2020, no vendors represented at least 10% of inventory purchases.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. (“BioSante”), we recorded goodwill of \$1.8 million. As a result of our acquisition of WellSpring Pharma Services Inc., we recorded additional goodwill of \$1.7 million in 2018. We assess the recoverability of the carrying value of goodwill as of October 31st of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value during the six months ended June 30, 2021. No impairment losses were recognized during the three and six months ended June 30, 2021 and 2020.

Definite-lived Intangible Assets

The components of net definite-lived intangible assets are as follows:

	June 30, 2021		December 31, 2020		Weighted Average Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
(in thousands)					
Acquired ANDA intangible assets	\$ 106,415	\$ (48,579)	\$ 106,415	\$ (42,367)	8.8 years
NDAs and product rights	242,372	(125,456)	230,974	(112,483)	9.9 years
Marketing and distribution rights	17,157	(11,866)	17,157	(11,386)	5.7 years
Non-compete agreement	624	(468)	624	(423)	7.0 years
	<u>\$ 366,568</u>	<u>\$ (186,369)</u>	<u>\$ 355,170</u>	<u>\$ (166,659)</u>	<u>9.4 years</u>

Definite-lived intangible assets are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets. In the case of certain New Drug Application (“NDA”) and product rights assets, we use an accelerated amortization method to better match the anticipated economic benefits expected to be provided. Amortization expense was \$10.1 million and \$10.0 million for the three months ended June 30, 2021 and 2020, respectively. Amortization expense was \$19.7 million and \$20.1 million for the six months ended June 30, 2021 and 2020, respectively. Refer to Note 12 for more details on acquired definite-lived intangible assets.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three and six months ended June 30, 2021 and 2020 and therefore no impairment loss was recognized in the three and six months ended June 30, 2021 and 2020.

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Expected future amortization expense is as follows:

(in thousands)	
2021	\$ 20,117
2022	36,828
2023	36,080
2024	33,103
2025	29,754
2026 and thereafter	24,317
Total	<u><u>\$ 180,199</u></u>

9. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of June 30, 2021, we had 0.2 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount.

The following table summarizes ESPP expense incurred under the 2016 Employee Stock Purchase Plan and included in our accompanying unaudited interim condensed consolidated statements of operations:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of sales	\$ 4	\$ 7	\$ 8	\$ 11
Research and development	6	12	11	19
Selling, general, and administrative	23	38	46	56
	<u><u>\$ 33</u></u>	<u><u>\$ 57</u></u>	<u><u>\$ 65</u></u>	<u><u>\$ 86</u></u>

Stock Incentive Plan

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”). As of June 30, 2021, 0.6 million shares of our common stock were available for issuance under the 2008 Plan.

From time to time, we may grant stock options to employees through an inducement grant outside of our 2008 Plan to induce prospective employees to accept employment with us (the “Inducement Grants”). The options are granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant date and are generally exercisable in four equal annual installments beginning on the first anniversary of the respective grant date. The grants are made pursuant to inducement grants outside of our shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

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The following table summarizes stock-based compensation expense incurred under the 2008 Plan and Inducement Grants included in our accompanying unaudited interim condensed consolidated statements of operations:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of sales	\$ 2	\$ 33	\$ 2	\$ 59
Research and development	149	146	263	333
Selling, general, and administrative	2,660	5,500	4,383	7,682
	\$ 2,811	\$ 5,679	\$ 4,648	\$ 8,074

A summary of stock option and restricted stock activity under the 2008 Plan and Inducement Grants during the six months ended June 30, 2021 and 2020 is presented below:

(in thousands)	Options	Inducement Grants	RSAs
Outstanding at December 31, 2019	757	—	192
Granted	7	—	261
Options Exercised/RSAs Vested	(8)	—	(121) ⁽¹⁾
Forfeited	(13)	—	(17)
Expired	—	—	—
Outstanding at June 30, 2020	743	—	315
Outstanding at December 31, 2020	756	180	352
Granted	84	61	457
Options Exercised/RSAs Vested	(5)	—	(111) ⁽²⁾
Forfeited	(58)	—	(53)
Expired	—	—	—
Outstanding at June 30, 2021	777	241	645

- (1) Includes 43 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the \$1.6 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.
- (2) Includes 25 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the \$0.8 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

10. INCOME TAXES

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of June 30, 2021, we have provided a valuation allowance against consolidated net deferred tax assets of \$0.3 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

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We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of June 30, 2021 and December 31, 2020. We are subject to taxation in various U.S. jurisdictions and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate, calculated on a worldwide consolidated basis, expected for the entire year. If we project taxable losses in any specific taxing jurisdiction, those losses are excluded from the calculation of the worldwide estimated annual effective tax rate and a resulting tax benefit is not recognized. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Prior to the adoption of new accounting guidance that we adopted on a prospective basis on January 1, 2021, during periods when we incurred net losses before income taxes, our annual estimated effective tax rate was at times adjusted based on the “loss limitation” requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that period. Under these provisions, our income tax benefit for the three months ended March 31, 2020 (but not for the three and six month periods ended June 30, 2020) was limited. The “loss limitation” requirements were removed by the new accounting guidance and, therefore, we were not required to assess any such limitation for 2021. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur. Global Intangible Low-Taxed Income (“GILTI”), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian operations is subject to U.S. taxes, with certain defined exemptions, thresholds and credits. For financial reporting purposes we have elected to treat GILTI inclusions as a period cost.

For the three months ended June 30, 2021, we recognized an income tax benefit of \$4.0 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 22.3% to pre-tax consolidated loss of \$18.2 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2021.

For the three months ended June 30, 2020, we recognized an income tax benefit of \$1.4 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 10.5% to pre-tax consolidated loss of \$13.8 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2020.

For the six months ended June 30, 2021, we recognized an income tax benefit of \$4.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 22.4% to pre-tax consolidated loss of \$18.1 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2021.

For the six months ended June 30, 2020, we recognized an income tax benefit of \$4.3 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 18.2% to pre-tax consolidated loss of \$23.6 million reported during the period, reduced by the net effects of certain discrete items

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occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2020.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of June 30, 2021 are classified as operating leases. As of June 30, 2021, we have nine material operating leases for facilities and office equipment with remaining terms expiring from 2022 through 2026 and a weighted average remaining lease term of 2.7 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 3.99% and 8.95%.

Rent expense for the three and six months ended June 30, 2021 and 2020 consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
(in thousands)				
Operating lease costs	\$ 43	\$ 57	\$ 92	\$ 109
Variable lease costs	13	14	21	29
Total lease costs	<u><u>\$ 56</u></u>	<u><u>\$ 71</u></u>	<u><u>\$ 113</u></u>	<u><u>\$ 138</u></u>

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2021	\$ 70
2022	127
2023	82
2024	56
2025 and thereafter	42
Total	<u><u>\$ 377</u></u>
Discount	(26)
Lease liability	351
Current lease liability	(128)
Non-current lease liability	<u><u>\$ 223</u></u>

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies, such as the Drug Enforcement Administration (“DEA”), the U.S. Food and Drug Administration (“FDA”), the Centers for Medicare and Medicaid Services (“CMS”), and Health Canada. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The DEA and Health Canada maintain oversight over our products that are considered controlled substances.

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone (“EEMT”) and Opium Tincture, are marketed without approved NDAs or Abbreviated New Drug Applications (“ANDAs”). During the three months ended June 30, 2021 and 2020, net revenues for these products totaled \$4.2 million and \$3.7 million, respectively. During the

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six months ended June 30, 2021 and 2020, net revenues for these products totaled \$8.0 million and \$8.1 million, respectively.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the three months ended June 30, 2021 and 2020 were \$0.6 million. Our contract manufacturing revenues for the group of unapproved products for the six months ended June 30, 2021 and 2020 were \$1.4 million and \$1.6 million, respectively.

Legal Proceedings

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, government reimbursement related actions and litigation. These matters are complex and subject to significant uncertainties. As such, we cannot accurately predict the outcome, or the effects of the legal proceedings described below. While we believe that we have valid claims and/or defenses in the litigation and other matters described below, litigation is inherently unpredictable, and the outcome of the proceedings could result in losses, including substantial damages, fines, civil or criminal penalties and injunctive or administrative remedies. We intend to vigorously prosecute and/or defend these matters, as appropriate, however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

Some of these matters with which we are involved are described below, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

From time to time, we are also involved in other pending proceedings for which, in our opinion based upon facts and circumstances known at the time, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to our results, and therefore remain undisclosed. If and when any reasonably possible losses associated with the resolution of such other pending proceedings, in our opinion, become material, we will disclose such matters.

Furthermore, like all pharmaceutical manufacturers, we are periodically exposed to product liability claims. The prevalence of these claims could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results. Recent trends in the product liability and director and officer insurance markets is to exclude matters related to certain classes of drugs, such as opioids. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.

Legal fees for litigation-related matters are expensed as incurred and included in the consolidated statements of operations under the selling, general, and administrative expense line item.

Commercial Litigation

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court for the District of Minnesota. The complaint alleges false advertising and unfair competition in violation of Section 43(a) of the Lanham Act, Section 1125(a) of Title 15 of the United States Code, and Minnesota State law, under the premise that we sold an unapproved Erythromycin Ethylsuccinate (“EES”) product during the

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period between September 27, 2016 and November 2, 2018. The complaint seeks a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profit, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019 and trial was scheduled to commence on August 25, 2021. As discussed in Note 14, Subsequent Event, we reached a settlement with Arbor on August 3, 2021 and therefore recognized an \$8.4 million legal settlement expense in our results of operations for the three months ended June 30, 2021.

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints are substantively identical. The plaintiffs in these actions allege that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. The complaints allege that the 2013 patent litigation settlement agreement between Forest and Amerigen violates federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs allege they paid higher prices as a result of delayed generic competition. Plaintiffs seek damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints do not specify the amount of damages sought from the Company or other defendants and the Company at this early stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases have been consolidated in the United States District Court for the Southern District of New York as In re Bystolic Antitrust Litigation, Case No. 20-cv-005735 (LJL). On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints, which are pending before the court for decision. The Company disputes any liability in these matters.

On March 24, 2021, Azurity Pharmaceuticals, Inc. ("Azurity") filed a complaint in the United States District Court for the District of Minnesota against ANI Pharmaceuticals, Inc., asserting that ANI's vancomycin hydrochloride oral solution drug product infringes U.S. Patent No. 10,688,046. The complaint seeks injunctive relief, damages, including lost profits and/or royalty, treble damages, and attorneys' fee and costs. Azurity has served its complaint, but ANI has not yet filed an answer and intends to dispute any liability.

Industry Related Litigation

In July 2020, we were served with a complaint brought by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including the Company. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease. As damages, New Mexico asks that the defendants fund this medical monitoring program. The negligence claims assert that the defendants were negligent in selling the product, essentially alleging that it was unreasonable to have the product on the market. With respect to that claim, New Mexico asserts that it paid for ranitidine products through state-funded insurance and health-care programs. On December 15, 2020, the case was removed to federal court and transferred to the In re Zantac multidistrict litigation ("MDL") pending in the United States District Court for the Southern District of Florida. New Mexico moved for remand to state court. The MDL court granted the remand motion on February 25, 2021. On April 16, 2021, New Mexico filed an amended complaint in the New Mexico First Judicial District Court in Santa Fe County. It did not name ANI in the amended complaint, effectively voluntarily dismissing ANI from the action. In December 2020, the City of Baltimore served ANI with a complaint against manufacturers and sellers of ranitidine products. The City of Baltimore complaint tracks the allegations of the New Mexico complaint. The

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Baltimore action was removed to federal court and transferred to the In re Zantac MDL on February 1, 2021. The City of Baltimore moved for remand, which was granted on April 1, 2021. The parties stipulated to allow the City of Baltimore to file an amended complaint in the Circuit Court of Maryland for Baltimore City in “due course,” without a specific filing deadline. On June 23, 2021, the City of Baltimore filed an amended complaint. The City of Baltimore did not name ANI in its amended complaint, effectively voluntarily dismissing ANI from the action. We dispute any liability in these matters.

Product Liability Related Litigation

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, have faced allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA’s February 2009 Black Box warning requirement (“legacy claims”). All these original legacy claims were settled or closed out, including a series of claims in California that were resolved by coordinated proceeding and settlement. Our insurance company assumed the defense of the legacy claims and paid all losses in settlement of the California legacy claims. In March 2019, we were served with a lawsuit in the Superior Court of California, County of Riverside, adding us as a defendant in a complaint filed in July 2017 that is alleged not to have been part of the original settled legacy claims. This new claim was dismissed with prejudice in July 2021 and the matter is now closed.

In June 2020, we were served with a personal injury complaint in the case of Koepsel v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-80882-RLR, filed in the United States District Court for Southern District of Florida, in which the plaintiff alleges that he developed kidney cancer in 2018 as a result of taking over the counter medication containing ranitidine. The Koepsel action was filed within an existing multidistrict litigation concerning ranitidine-containing drugs pending in the Southern District of Florida before Judge Robin L. Rosenberg, In re Zantac MDL, 20 MDL 2924. A Master Personal Injury Complaint (“MPIC”) in that MDL that was filed on June 22, 2020 also named the Company as a defendant. The Company was dismissed from the Koepsel case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended Master Personal Injury Complaint was filed on February 8, 2021, which does not name ANI. The Company has been named in other individual personal injury complaints filed in MDL 20 MD 2924 in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. To date, the Company has been served with complaints in five of those additional cases: Cooper v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020), Lineberry v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), Lovette v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), Hightower v. Pfizer, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-82214-RLR (served December 16, 2020) and Bird v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-80837-RLR (served December 30, 2020). We have informed counsel for the plaintiffs that we did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited two-month period of time, from July 2019 to September 2019. Our product was voluntarily recalled in January 2020. Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and we have informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the Cooper, Lineberry and Lovette actions on November 20, 2020. ANI was voluntarily dismissed from the Bird action on March 15, 2021 and from the Hightower action on March 29, 2021. After ANI had been voluntarily dismissed from all complaints served on it in the MDL, the district court dismissed all claims against the generic manufacturer defendants with prejudice on preemption grounds by opinion dated July 8, 2021. We dispute any liability in these MDL matters.

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Other Industry Related Matters

On or about September 20, 2017, the Company and certain of its employees were served with search warrants and/or grand jury subpoenas to produce documents and possibly testify relating to a federal investigation of the generic pharmaceutical industry. We have been cooperating and intend to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

12. FAIR VALUE DISCLOSURES

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework that prioritizes and ranks the level of observability of inputs used in measuring fair value.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Loan, DDTL, and Revolver bear an interest rate that fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at June 30, 2021.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante and expire in June 2023, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result.

The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of June 30, 2021 and December 31, 2020. We also determined that the changes in such fair value were immaterial in the three and six months ended June 30, 2021 and 2020.

In April 2020, we terminated two interest rate swaps used to manage interest rate exposure on underlying interest payments for our Term Loan and DDTL and entered into one new interest rate swap agreement to manage our total exposure under these borrowings (Note 5). The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was a \$9.0 million liability at June 30, 2021.

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The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of June 30, 2021 and December 31, 2020, by level within the fair value hierarchy:

(in thousands) <u>Description</u>	<u>Fair Value at June 30, 2021</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Liabilities				
Interest rate swaps	\$ 9,040	\$ —	\$ 9,040	\$ —
CVRs	\$ —	\$ —	\$ —	\$ —
 Description	 <u>Fair Value at December 31, 2020</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Liabilities				
Interest rate swaps	\$ 14,109	\$ —	\$ 14,109	\$ —
CVRs	\$ —	\$ —	\$ —	\$ —

Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

We do not have any financial assets and liabilities that are measured at fair value on a non-recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We do not have any non-financial assets and liabilities that are measured at fair value on a recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

We measure our long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and six months ended June 30, 2021 and 2020.

Acquired Non-Financial Assets Measured at Fair Value

In April 2021, we acquired three NDAs and an ANDA and certain related inventories from Sandoz, Inc. for total consideration of \$20.7 million. We also incurred and paid \$0.4 million in transaction costs directly related to the acquisition. The acquisition was funded via borrowings under our Revolver. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized \$11.4 million as acquired intangible assets and \$9.7 million of inventory at fair value, including \$0.6 million of API, \$1.0 million of sample inventory, and \$8.1 million in finished goods inventory. In order to determine the fair value of the intangible assets, we used the present value of the estimated cash flows related to the product rights using a discount rate of 10%, which are level 3 unobservable inputs. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The intangible assets are being amortized in full over a useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2021 and therefore no impairment loss was recognized for the six months ended June 30, 2021.

In July 2020, we acquired an ANDA and certain related inventories from a private company for total consideration of \$4.3 million. We also incurred and paid \$0.1 million in transaction costs directly related to the acquisition. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the

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acquisition. We recognized \$3.0 million as an acquired ANDA intangible asset and \$1.4 million in inventory at fair value. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The ANDA is being amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2021 and therefore no impairment loss was recognized for the six months ended June 30, 2021.

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. (“Amerigen”) for a purchase consideration of \$56.8 million and up to \$25.0 million in contingent payments over the next four years. Payments were made using cash on hand and through borrowings of \$15.0 million under our Revolver. We also incurred and paid \$0.7 million in transaction costs directly related to the acquisition. We accounted for the transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized \$38.5 million as acquired ANDA intangible assets and \$6.7 million as acquired marketing and distribution rights related to the licensed products, which are being amortized over their useful lives of seven years. We also recognized \$3.8 million of the purchase price as research and development expense because certain of the generic products had significant remaining work required in order to be commercialized and the products did not have an alternative future use. The payment was allocated to the two asset categories and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. To determine the fair value of the acquired intangible assets and in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 8%. We also recognized \$8.4 million in inventory at fair value, including \$1.7 million of API and \$6.7 million of finished goods. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. Contingent liabilities will be accrued when they are both estimable and probable. The intangible assets will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2021 and therefore no impairment loss was recognized for the six months ended June 30, 2021.

13. CORTROPHIN PRE-LAUNCH CHARGES

In January 2016, we acquired the right, title and interest in the NDAs for Cortrophin Gel and Cortrophin-Zinc. Subsequently, we have assembled a Cortrophin re-commercialization team of scientists, executed a long-term supply agreement with a supplier of pig pituitary glands, our primary raw material for corticotrophin API, executed a long-term supply agreement with an API manufacturer, with whom we have advanced the manufacture of corticotropin API via manufacture of commercial-scale batches, and executed a long-term commercial supply agreement with a current good manufacturing practice (“cGMP”) aseptic fill contract manufacturer.

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts were consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to continue in 2021 as we build raw materials, API and finished goods for the expected launch of this product. During the three and six months ended June 30, 2021, we incurred \$0.5 million and \$0.6 million, respectively, of charges for the purchase of materials. During the three and six months ended June 30, 2020, we incurred \$3.6 million and \$8.2 million, respectively in charges for the purchase of materials. Due to the inherent uncertainty of the timing of FDA approval for this product, we cannot reasonably predict whether these materials will ultimately be eligible for use in commercial finished goods inventory. We also incurred other charges directly related to the Cortrophin pre-launch commercialization efforts, including, but not

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limited to, sales and marketing and consulting expenses. During the three and six months ended June 30, 2021, we incurred \$2.5 million and \$2.6 million, respectively, of these charges, which are included on the unaudited interim condensed consolidated statements of operations as a selling, general, and administrative expense. There were no comparable expenses in 2020.

14. SUBSEQUENT EVENT

On August 3, 2021, the Company entered into a Settlement Agreement with Arbor Pharmaceuticals, LLC to resolve all claims related to Civil Action 17-4910, Arbor Pharmaceuticals, LLC (“Arbor”) v. ANI Pharmaceuticals, Inc., which was pending trial in the United States District Court for the District of Minnesota. Under the terms of the agreement, ANI will pay Arbor \$8.4 million and Arbor will dismiss the action with prejudice. Neither party admitted wrongdoing in reaching this settlement. The Company will pay the settlement from cash on the balance sheet.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, the audited consolidated financial statements and the accompanying notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "2020 Annual Report"), as well as the information contained under Management's Discussion and Analysis of Financial Condition and Results of Operations and "Risk Factors" contained in the 2020 Annual Report, and Part II, Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q, and other information provided from time to time in our other filings with the SEC. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our 2020 Annual Report and this Quarterly Report on Form 10-Q.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities, including controlled substances, oncology products (anti-cancer), hormones and steroids, and complex formulations. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

Strategy

Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our growth strategy is driven by the following key pillars:

Building a successful Cortrophin Gel franchise

We acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016 and executed long-term supply agreements with a supplier of our primary raw material for corticotrophin active pharmaceutical ingredient ("API"), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. In April 2020, the FDA issued a Refusal to File ("RTF") letter for our supplemental New Drug Application ("sNDA") for Cortrophin Gel. Subsequently, we retained a prominent regulatory consulting firm, restructured the internal Cortrophin development team, and focused our efforts on a comprehensive review of the original sNDA to execute a plan that addressed all gaps for a planned re-submission to the FDA. During the second quarter of 2021, we re-submitted the sNDA to the FDA.

We have begun to invest in leadership and expertise in the areas of commercialization of rare disease therapies to develop a launch strategy and commercial plan for this product.

Strengthening our generics business with enhanced research and development capability and increased focus on niche opportunities

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous NDAs through asset acquisitions, including, most recently, the U.S. portfolio of 23 generic products, including 10 commercial products at the time of the acquisition, from Amerigen Pharmaceuticals, Ltd. We also focus on niche lower competition opportunities such as injectables and Paragraph IV filings. Additionally, we will seek opportunities to enhance our research and development capabilities through strategic partnerships and acquisitions of assets and businesses.

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Maximizing the value from our established brands through innovative “go-to-market” (“GTM”) strategies and continued programmatic acquisitions

We have acquired the New Drug Applications (“NDAs”) for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, OXISTAT, VEREGEN, and Pandel. We are innovating in our GTM strategy through creative partnerships. In addition, we will continue to explore opportunities in acquiring new brands to grow our established brands portfolio.

Expansion of contract development and manufacturing organization (“CDMO”) business by leveraging our unique manufacturing capabilities

We built a CDMO business through our sites in Baudette and grew it through the acquisition of WellSpring Pharma Services Inc. (“ANI Canada”). Our North America based manufacturing and unique capabilities in high-potency, hormonal, steroid, and oncolytic products can be leveraged to expand our CDMO business.

The pillars of our strategy will be enabled by an empowered, collaborative, and purposeful team with high performance-orientation.

Product Development Considerations

We consider a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include:

- ***Formulation Complexity.*** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.
- ***Patent Status.*** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.
- ***Market Size.*** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.
- ***Profit Potential.*** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our anticipated market share, pricing, including the expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.
- ***Manufacturing.*** We generally seek to develop and manufacture products at our own manufacturing plants in order to optimize the utilization of our facilities, ensure quality control in our products, and maximize profit potential.
- ***Competition.*** When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

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Recent Developments

Pending Business Acquisition

On March 8, 2021, we entered into a definitive agreement to acquire Novitium Pharma LLC (“Novitium”), a privately held New Jersey-based pharmaceutical company with development, manufacturing, and commercial capabilities (the “Acquisition”). The closing of the acquisition will occur (a) within five business days after all of the conditions to the closing set forth in the merger agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by us and Novitium, subject to the completion of a minimum period. The closing is subject to the satisfaction of customary closing conditions and necessary regulatory approvals and we expect it to close in the second half of 2021.

Consideration will consist of a combination of (i) an estimated cash amount of \$89.5 million, subject to various adjustments and expected to be financed by a \$25.0 million private placement of preferred stock (the “PIPE Investment”) and new debt financing, both described below, (ii) an aggregate of 2,466,667 shares of ANI common stock, and (iii) up to \$46.5 million in contingent future earn-out payments.

We will finance the transaction with a new \$340.0 million Senior Secured Credit Facility (the “New Facility”), consisting of a \$300.0 million term loan and a \$40.0 million revolving credit facility, the issuance of 2,466,667 shares of ANI common stock (approximately \$74.0 million in value based on a \$30 stock price), and a \$25.0 million PIPE Investment by Ampersand 2020 Limited Partnership (“Ampersand”), an affiliate of Ampersand Capital Partners. The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI’s existing senior credit facilities. The term loan portion of the New Facility, which was successfully syndicated on May 24, 2021, represents fully committed capital and, as such, carries customary ticking fees that commence 45 days and 90 days post allocation.

Concurrently with the execution of the definitive agreement, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand (the “PIPE Investor”), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock, for a purchase price of \$1,000 per share and an aggregate purchase price of \$25.0 million PIPE Investment.

The PIPE Investment and issuance of shares of ANI common stock were approved by ANI shareholders at the June 2021 Annual Meeting of Stockholders.

As of the date of filing of this quarterly report on Form 10-Q, the Acquisition remains under review by the U.S. Federal Trade Commission and we remain actively engaged in discussions with the commission.

For more information about the pending Novitium acquisition transaction, please see our [Form 8-K filed with the SEC on March 9, 2021](#).

NDA Acquisition

On April 1, 2021, we acquired the NDAs for OXISTAT®, VEREGEN®, and Pandel® and the ANDA for Apexicon® from Sandoz Inc. for total consideration of \$20.7 million. The acquisition was funded through a \$24 million borrowing under our pre-existing Revolver.

Cortrophin Gel Re-commercialization Update

In April 2020, the U.S. Food and Drug Administration (“FDA”) issued a Refusal to File (“RTF”) letter for our Supplemental New Drug Application (“sNDA”) for Cortrophin Gel. Subsequently, we retained a prominent regulatory consulting firm, restructured the internal Cortrophin development team, and focused our efforts on a comprehensive review of the original sNDA to execute a plan that addressed all gaps for a planned re-submission to the FDA. During the second quarter of 2021, we re-submitted the sNDA to the FDA.

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In addition, in the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to continue in 2021 as we build raw materials, API and finished goods for the expected launch of this product.

COVID-19 Impact

We continue to closely monitor the impact of the novel coronavirus (“COVID-19”) pandemic on our business and the geographic regions where we operate. During the three months ended March 31, 2021 per IQVIA/IMS data, total market generic prescriptions in the United States declined when compared to the three months ended December 31, 2020 and March 31, 2020. Over these same periods, total market brand prescriptions were steady or increased. The decline in generic prescriptions, which generally make up 70-80% of our net revenues, during this period was in part attributable to the COVID-19 pandemic, as subsequent waves impacted patient and customer behavior. The decline in generic prescriptions due to the COVID-19 pandemic negatively impacted our generic net revenues during the three months ended March 31, 2021. During the three months ended June 30, 2021, per IQVIA/IMS data, total market generic and brand prescriptions increased when compared to the three months ended March 31, 2021 and the three months ended June 30, 2020, in part due to easing of local restrictions and availability of COVID-19 vaccines. We have not experienced a significant impact to our manufacturing operations; however, we continue to see minor disruptions to our supply chain from the COVID-19 pandemic during 2021. Our manufacturing facilities in Baudette, Minnesota and Oakville, Ontario have remained open throughout the pandemic and have operated in accordance with local, state and national safety guidelines. The pandemic has not impacted our access to capital and has not significantly impacted our use of funds, including but not limited to capital expenditures, spend on research and development activities and business development opportunities.

We are unable to predict the impact that the COVID-19 pandemic will continue to have on our future financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and continued duration of the pandemic, the level of success of continued actions taken to contain the pandemic or mitigate its impact, including the availability and usage of vaccines, and the direct and indirect economic effects of the pandemic and containment measures, among others. The outbreak of COVID-19 in many countries, including the United States and Canada, has had a significant adverse impact on global economic activity and has contributed to significant volatility and negative pressure in financial markets. As a result, the COVID-19 pandemic has negatively impacted almost every industry, either directly or indirectly. Further, the impacts of a potential worsening of global economic conditions and the continued disruptions to, and volatility in, the credit and financial markets, pharmaceutical supply chains, patient access to healthcare as well as other unanticipated consequences remain unknown.

Settlement of Pending Litigation

On August 3, 2021, the Company entered into a Settlement Agreement with Arbor Pharmaceuticals, LLC to resolve all claims related to Civil Action 17-4910, Arbor Pharmaceuticals, LLC (“Arbor”) v. ANI Pharmaceuticals, Inc., which was pending trial in the United States District Court for the District of Minnesota. Under the terms of the agreement, ANI will pay Arbor \$8.4 million and Arbor will dismiss the action with prejudice. Neither party admitted wrongdoing in reaching this settlement. The Company will pay the settlement from cash on the balance sheet. We recognized the \$8.4 million settlement as legal settlement expense on the unaudited interim condensed consolidated statements of operations in the three months ended June 30, 2021.

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GENERAL

The following table summarizes our results of operations for the periods indicated:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenues	\$ 48,625	\$ 48,470	\$ 103,146	\$ 98,244
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	22,314	20,695	42,299	42,499
Research and development	2,805	3,035	5,773	9,379
Selling, general, and administrative	18,820	21,213	36,407	34,896
Depreciation and amortization	11,324	11,198	22,222	22,381
Legal settlement expense	8,400	—	8,400	—
Cortrophin pre-launch charges	515	3,636	553	8,238
Operating loss	(15,553)	(11,307)	(12,508)	(19,149)
Interest expense, net	(2,531)	(2,356)	(4,985)	(4,388)
Other expense, net	(67)	(116)	(582)	(106)
Loss before benefit for income taxes	(18,151)	(13,779)	(18,075)	(23,643)
Benefit for income taxes	4,045	1,443	4,055	4,296
Net loss	<u><u>\$ (14,106)</u></u>	<u><u>\$ (12,336)</u></u>	<u><u>\$ (14,020)</u></u>	<u><u>\$ (19,347)</u></u>

The following table sets forth, for all periods indicated, items in our unaudited interim condensed consolidated statements of operations as a percentage of net revenues:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	100.0 %	100.0 %	100.0 %	100.0 %
Net revenues				
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	45.9 %	42.7 %	41.0 %	43.3 %
Research and development	5.8 %	6.3 %	5.6 %	9.5 %
Selling, general, and administrative	38.7 %	43.8 %	35.3 %	35.5 %
Depreciation and amortization	23.3 %	23.1 %	21.5 %	22.8 %
Legal settlement expense	17.3 %	— %	8.1 %	— %
Cortrophin pre-launch charges	1.1 %	7.5 %	0.5 %	8.4 %
Operating loss	(32.1)%	(23.4)%	(12.0)%	(19.5)%
Interest expense, net	(5.2)%	(4.9)%	(4.8)%	(4.5)%
Other expense, net	(0.1)%	(0.2)%	(0.6)%	(0.1)%
Loss before benefit for income taxes	(37.4)%	(28.5)%	(17.4)%	(24.1)%
Benefit for income taxes	8.3 %	3.0 %	3.9 %	4.4 %
Net loss	<u><u>(29.1)%</u></u>	<u><u>(25.5)%</u></u>	<u><u>(13.5)%</u></u>	<u><u>(19.7)%</u></u>

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RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2021 AND 2020

Net Revenues

(in thousands)	Three Months Ended June 30,			% Change
	2021	2020	Change	
Generic pharmaceutical products	\$ 34,199	\$ 33,400	\$ 799	2.4 %
Branded pharmaceutical products	11,038	10,633	405	3.8 %
Contract manufacturing	2,322	2,900	(578)	(19.9)%
Royalty and other	1,066	1,537	(471)	(30.6)%
Total net revenues	<u>\$ 48,625</u>	<u>\$ 48,470</u>	<u>\$ 155</u>	<u>0.3 %</u>

We derive substantially all of our revenues from sales of generic and branded pharmaceutical products, contract manufacturing, and contract services, which include product development services, laboratory services, and royalties on net sales of certain products.

Net revenues for the three months ended June 30, 2021 were \$48.6 million compared to \$48.5 million for the same period in 2020, an increase of 0.3%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$34.2 million during the three months ended June 30, 2021, an increase of 2.4% compared to \$33.4 million for the same period in 2020. From a product perspective, the net increase was due to increased sales of Fenofibrate, Potassium Citrate Extended Release, Vancomycin Oral Solution, and the second quarter 2021 launch of Nicardipine. These increases were partially offset by declines in sales of Methazolamide, Miglustat, Penicillamine, and Mixed Amphetamine Salts.

During the three months ended June 30, 2020, the overall generic pharmaceutical product market and our net revenues for generic pharmaceutical products, which generally make up 70-80% of our net revenues, were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in suppressed generic prescriptions during the three months ended June 30, 2020. During the three months ended June 30, 2021, generic prescription levels on a total market basis increased when compared to the immediately prior three-month period and the comparable three-month period in 2020. Net revenues during the three months ended June 30, 2021 were negatively impacted by decreases in average selling prices and a shift in mix towards products with lower average selling prices, tempered by increased volumes.

- Net revenues for branded pharmaceutical products were \$11.0 million during the three months ended June 30, 2021, an increase of 3.8% compared to \$10.6 million for the same period in 2020. The primary reason for the increase was the launch of the products acquired in the Sandoz, Inc. acquisition in the second quarter 2021 and increased sales of InnoPran XL. These increases were tempered by decreased revenues from sales of Atacand and Arimidex.

During the three months ended June 30, 2020, the overall brand pharmaceutical product market and our brand revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in suppressed brand prescriptions during the three months ended June 30, 2020. During the three months ended June 30, 2021, brand prescription levels on a total market basis increased when compared to the prior three-month period and the comparable three-month period in 2020. Net revenues during the three months ended June 30, 2021 were negatively impacted by a shift in mix towards product with lower average selling prices, tempered by increased volumes.

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- Contract manufacturing revenues were \$2.3 million during the three months ended June 30, 2021, a decrease of 19.9% compared to \$2.9 million for the same period in 2020, due to a decreased volume of orders from contract manufacturing customers in the period.
- Royalty and other revenues were \$1.1 million during the three months ended June 30, 2021, a decrease of \$0.4 million from \$1.5 million for the same period in 2020, primarily due to decreases in product development revenues earned by ANI Canada and the non-recurrence in royalty revenue related to Yescarta®. These decreases were tempered by licensing revenues earned during the three months ended June 30, 2021.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended June 30,			Change	% Change
	2021	2020			
Cost of sales (excl. depreciation and amortization)	\$ 22,314	\$ 20,695		\$ 1,619	7.8 %

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, packaging components, and royalties related to profit-sharing arrangements. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on our unaudited interim condensed statements of operations.

For the three months ended June 30, 2021, cost of sales increased to \$22.3 million from \$20.7 million for the same period in 2020, an increase of \$1.6 million, or 7.8%, primarily as a result of increased volumes in the current year period. The increase was tempered by a \$1.2 million decrease related to a decrease in sales of products subject to profit sharing arrangements. During the three months ended June 30, 2021 and 2020, we recognized \$1.5 million and \$1.4 million, respectively, in cost of sales representing the excess of fair value over cost for inventory acquired in acquisitions and subsequently sold during the three months ended June 30, 2021 and 2020, respectively.

Cost of sales as a percentage of net revenues increased to 42.8% during the three months ended June 30, 2021, from 39.8% during same period in 2020 (exclusive of cost of sales representing the excess of fair value over cost for inventory acquired in the acquisitions and subsequently sold during the period), primarily as a result of increased volumes in a period of declining average selling prices across generic and brand products and a shift in mix towards generic and brand products with lower average selling prices. The negative impacts were tempered by a decrease in sales of products subject to profit sharing arrangements.

During the three months ended June 30, 2021, no single vendor represented at least 10% of inventory purchases. During the three months ended June 30, 2020, we purchased approximately 13% of our inventory from one supplier.

Other Operating Expenses

(in thousands)	Three Months Ended June 30,			Change	% Change
	2021	2020			
Research and development	\$ 2,805	\$ 3,035		\$ (230)	(7.6)%
Selling, general, and administrative	18,820	21,213		(2,393)	(11.3)%
Depreciation and amortization	11,324	11,198		126	1.1 %
Legal settlement expense	8,400	—		8,400	NM ⁽¹⁾
Cortrophin pre-launch charges	515	3,636		(3,121)	(85.8)%
Total other operating expenses	<u>\$ 41,864</u>	<u>\$ 39,082</u>		<u>\$ 2,782</u>	<u>7.1 %</u>

⁽¹⁾ Not Meaningful

Other operating expenses consist of research and development costs, selling, general, and administrative expenses, depreciation and amortization, and Cortrophin pre-launch charges.

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For the three months ended June 30, 2021, other operating expenses increased to \$41.9 million from \$39.1 million for the same period in 2020, an increase of \$2.8 million, or 7.1%, primarily as a result of the following factors:

- Research and development expenses decreased from \$3.0 million to \$2.8 million, a decrease of 7.6%, primarily due to the non-recurrence of \$0.4 million of 2020 severance related expense associated with the restructuring of our internal Cortrophin development team.
- Selling, general, and administrative expenses decreased from \$21.2 million to \$18.8 million, a decrease of \$2.4 million, or 11.3%, primarily due to the non-recurrence of \$6.5 million of termination benefit expenses related to the 2020 departure of our former President and CEO. We also incurred recruitment and related legal charges associated with our CEO search in the second quarter 2020. These decreases were offset by \$1.7 million of transaction expenses related to the pending Novitium acquisition and \$2.5 million in sales and marketing expenses related to Cortrophin pre-launch activities incurred during the three months ended June 30, 2021.
- Depreciation and amortization increased from \$11.2 million to \$11.3 million, an increase of 1.1%, primarily due to the amortization of the NDAs acquired in April 2021 from Sandoz Inc., partially offset by assets that became fully amortized in 2020.
- As described in Note 14, *Subsequent Event*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Legal settlement expense of \$8.4 million in the three months ended June 30, 2021. No Legal settlement expenses were recognized in the three months ended June 30, 2020.
- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Cortrophin pre-launch charges of \$0.5 million in the three months ended June 30, 2021. We recognized Cortrophin pre-launch charges of \$3.6 million in the three months ended June 30, 2020.

Other Expense, net

(in thousands)	<u>Three Months Ended June 30,</u>			
	<u>2021</u>	<u>2020</u>	<u>Change</u>	<u>% Change</u>
Interest expense, net	\$ (2,531)	\$ (2,356)	\$ (175)	7.4 %
Other expense, net	(67)	(116)	49	(42.2)%
Total other expense, net	<u>\$ (2,598)</u>	<u>\$ (2,472)</u>	<u>\$ (126)</u>	<u>5.1 %</u>

For the three months ended June 30, 2021, we recognized other expense of \$2.6 million versus other expense of \$2.5 million for the same period in 2020, an increase of \$0.1 million. Interest expense, net for the three months ended June 30, 2021 and 2020 consists primarily of interest expense on borrowings under our secured term loan (“Term Loan”), delayed draw term loan (“DDTL”), and line of credit (“Revolver”). For the three months ended June 30, 2021 and 2020, there was less than \$0.1 million of interest capitalized into construction in progress.

Benefit for Income Taxes

(in thousands)	<u>Three Months Ended June 30,</u>			
	<u>2021</u>	<u>2020</u>	<u>Change</u>	<u>% Change</u>
Benefit for income taxes	\$ 4,045	\$ 1,443	\$ 2,602	180.3 %

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance.

For the three months ended June 30, 2021, we recognized an income tax benefit of \$4.0 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 22.3% to pre-tax consolidated loss of \$18.2

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million reported during the period, reduced by the net effects of certain discrete items occurring in 2021 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2021.

For the three months ended June 30, 2020, we recognized an income tax benefit of \$1.4 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 10.5% to pre-tax consolidated loss of \$13.8 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2020.

Net Revenues

(in thousands)	Six Months Ended June 30,			% Change
	2021	2020	Change	
Generic pharmaceutical products	\$ 66,812	\$ 70,895	\$ (4,083)	(5.8)%
Branded pharmaceutical products	18,555	19,790	(1,235)	(6.2)%
Contract manufacturing	4,895	4,874	21	0.4 %
Royalty and other income	12,884	2,685	10,199	379.9 %
Total net revenues	<u><u>\$ 103,146</u></u>	<u><u>\$ 98,244</u></u>	<u><u>\$ 4,902</u></u>	<u><u>5.0 %</u></u>

Net revenues for the six months ended June 30, 2021 were \$103.1 million compared to \$98.2 million for the same period in 2020, an increase of \$4.9 million, or 5.0%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$66.8 million during the six months ended June 30, 2021, a decrease of 5.8% compared to \$70.9 million for the same period in 2020. From a product perspective, the net decrease was driven by declines in sales of Ezetimibe Simvastatin, Methazolamide, Miglustat, and Mixed Amphetamine Salts, and tempered by increased revenues from sales of Fenofibrate, Paliperidone Extended Release, Potassium Citrate Extended Release, and the second quarter 2021 launch of Nicardipine.

During the six months ended June 30, 2020, and primarily the three months ended June 30, 2020, the overall generic pharmaceutical product market and our net revenues from generic pharmaceutical products were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in suppressed generic prescriptions during the six months ended June 30, 2020. During the six months ended June 30, 2021, generic prescription levels on a total market basis decreased when compared to the comparable six-month period in 2020. Based upon an analysis of IQVIA/IMS data, during the three months ended March 31, 2021, the total market for generic prescriptions in the United States declined approximately 9% when compared to the three months ended March 31, 2020. We believe that this overall decline in prescription activity during this period was principally due to the COVID-19 pandemic, and it negatively impacted the market for many of our generic pharmaceutical products. Total generic market prescriptions increased during the three months ended June 30, 2021 when compared to the prior year comparable period. Net revenues during the six months ended June 30, 2021 were negatively impacted by decreases in average selling prices and a shift in mix towards products with lower average selling prices, tempered by increased volumes.

- Net revenues for branded pharmaceutical products were \$18.6 million during the six months ended June 30, 2021, a decrease of 6.2% compared to \$19.8 million for the same period in 2020. The primary reasons for the decrease were lower unit sales of Inderal XL and decreased unit sales of Atacand. These decreases were tempered by the launch of the products acquired in the Sandoz, Inc. acquisition in the second quarter 2021.

During the six months ended June 30, 2020, the overall brand pharmaceutical product market and our brand revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in suppressed brand prescriptions during the three months ended June 30, 2020. During the six months ended June

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30, 2021, brand prescription levels on a total market basis increased when compared to the prior six-month period and the comparable six-month period in 2020. Net revenues during the six months ended June 30, 2021 were negatively impacted by a shift in mix towards product with lower average selling prices, tempered by increased volumes.

- Contract manufacturing revenues were \$4.9 million during the six months ended June 30, 2021, materially unchanged compared to \$4.9 million for the same period in 2020.
- Royalty and other revenues were \$12.9 million during the six months ended June 30, 2021, an increase of \$10.2 million from \$2.7 million for the same period in 2020, primarily due to the recognition of the final royalty related to the Kite Pharma, Inc. license agreement (Yescarta®) pursuant to the Tripartite Agreement in the first quarter 2021.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Six Months Ended June 30,			<u>Change</u>	<u>% Change</u>
	<u>2021</u>	<u>2020</u>	<u>\$</u>		
Cost of sales (excl. depreciation and amortization)	\$ 42,299	\$ 42,499	\$ (200)		(0.5)%

For the six months ended June 30, 2021, cost of sales decreased to \$42.3 million from \$42.5 million for the same period in 2020, a decrease of \$0.2 million, or 0.5%. During the six months ended June 30, 2021, we incurred \$1.5 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Sandoz, Inc. acquisition and subsequently sold during the period, compared to \$4.1 million during the six months ended June 30, 2020, related to the Amerigen acquisition. Excluding these impacts, the cost of sales increase during the six months ended June 30, 2021 was due primarily to increased volumes during the current year period and tempered by a \$1.3 million decrease in inventory reserve charges related to excess and obsolete inventory and discontinued projects.

Cost of sales as a percentage of net revenues increased to 39.6% during the six months ended June 30, 2021, from 39.1% during same period in 2020 (exclusive of cost of sales representing the excess of fair value over cost for inventory acquired in the acquisitions and subsequently sold during the period), primarily as a result of increased volumes in a period of declining average selling prices across generic and brand products and a shift in mix towards generic and brand products with lower average selling prices. The negative impacts were significantly tempered by \$11.2 million of royalty revenue in the first quarter 2021 with no associated cost of sales.

During the six months ended June 30, 2021, no single vendor represented at least 10% of inventory purchases. During the six months ended June 30, 2020, no vendors represented at least 10% of inventory purchases.

Other Operating Expenses

(in thousands)	Six Months Ended June 30,			<u>Change</u>	<u>% Change</u>
	<u>2021</u>	<u>2020</u>	<u>\$</u>		
Research and development	\$ 5,773	\$ 9,379	\$ (3,606)		(38.4)%
Selling, general, and administrative	36,407	34,896	1,511		4.3 %
Depreciation and amortization	22,222	22,381	(159)		(0.7)%
Legal settlement expense	8,400	—	8,400		NM ⁽¹⁾
Cortrophin pre-launch charges	553	8,238	(7,685)		(93.3)%
Total other operating expenses	<u>\$ 73,355</u>	<u>\$ 74,894</u>	<u>\$ (1,539)</u>		<u>(2.1)%</u>

(2) Not Meaningful

For the six months ended June 30, 2021, other operating expenses decreased to \$73.4 million from \$74.9 million for the same period in 2020, a decrease of \$1.5 million, or 2.1%, primarily as a result of the following factors:

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- Research and development expenses decreased from \$9.4 million to \$5.8 million, a decrease of 38.4%, primarily due to the non-recurrence of the \$3.8 million in-process research and development expense from the Amerigen Pharmaceuticals, Ltd. acquisition in the first quarter 2020.
- Selling, general, and administrative expenses increased from \$34.9 million to \$36.4 million, an increase of \$1.5 million, or 4.3%, primarily due to the \$4.6 million of transaction expenses related to the pending Novitium acquisition and \$2.6 million in sales and marketing expenses related to Cortrophin pre-launch activities incurred in the six months ended June 30, 2021, as well as increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, and increased legal, insurance, and other professional fees. These increases were offset by the non-recurrence of \$6.5 million of termination benefit expenses related to the departure of our former President and CEO and non-recurrence of other recruitment and related legal charges associated with our CEO search in the second quarter 2020.
- Depreciation and amortization decreased from \$22.4 million to \$22.2 million, a decrease of \$0.2 million, primarily due to assets that became fully amortized in 2020, partially offset by the amortization of the NDAs acquired in April 2021 from Sandoz Inc.
- As described in Note 14, *Subsequent Event*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Legal settlement expense of \$8.4 million in the six months ended June 30, 2021. No Legal settlement expenses were recognized in the six months ended June 30, 2020.
- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Cortrophin pre-launch charges of \$0.6 million in the six months ended June 30, 2021. We recognized Cortrophin pre-launch charges of \$8.2 million in the six months ended June 30, 2020.

Other Expense, net

(in thousands)	Six Months Ended June 30,		Change	% Change
	2021	2020		
Interest expense, net	\$ (4,985)	\$ (4,388)	\$ (597)	13.6 %
Other expense, net	(582)	(106)	(476)	449.1 %
Total other expense, net	<u>\$ (5,567)</u>	<u>\$ (4,494)</u>	<u>\$ (1,073)</u>	<u>23.9 %</u>

For the six months ended June 30, 2021, we recognized other expense of \$5.6 million versus other expense of \$4.5 million for the same period in 2020, an increase of \$1.1 million, due in part to increased interest expense on borrowings on our Revolver. Interest expense, net for the six months ended June 30, 2021 and 2020 consists primarily of interest expense on borrowings under our Term Loan, DDTL, and Revolver. For the six months ended June 30, 2021 and 2020 there was less than \$0.1 million of interest capitalized into construction in progress.

Benefit for Income Taxes

(in thousands)	Six Months Ended June 30,		Change	% Change
	2021	2020		
Benefit for income taxes	\$ 4,055	\$ 4,296	\$ (241)	(5.6)%

For the six months ended June 30, 2021, we recognized an income tax benefit of \$4.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 22.4% to pre-tax consolidated loss of \$18.1 million reported during the period, reduced by the net effects of certain discrete items occurring in 2021 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2021.

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For the six months ended June 30, 2020, we recognized an income tax benefit of \$4.3 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 18.2% to pre-tax consolidated loss of \$23.6 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2020.

LIQUIDITY AND CAPITAL RESOURCES

On June 30, 2021, we had \$24.3 million in unrestricted cash and cash equivalents. On December 31, 2020, we had \$7.9 million in unrestricted cash and cash equivalents. In April 2021, we drew \$24.0 million under the Revolver. We generated \$20.9 million of cash from operations in the six months ended June 30, 2021. In April 2021, we acquired three NDAs and an ANDA and certain related inventories from Sandoz Inc. for total consideration of \$20.7 million. The acquisition was funded through borrowings under our Revolver. Subsequent to the June 30, 2021 balance sheet date, we utilized \$8.4 million of cash from the balance sheet to settle litigation with Arbor.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our revolving line of credit facility, under which \$43.5 million remains available for borrowing as of June 30, 2021, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

Cash Flows

The following table summarizes the net cash and cash equivalents provided by/(used in) by operating activities, investing activities, and financing activities for the periods indicated:

(in thousands)	Six Months Ended June 30,	
	2021	2020
Operating Activities	\$ 20,909	\$ 22,590
Investing Activities	\$ (22,687)	\$ (60,394)
Financing Activities	\$ 18,173	\$ 3,147

Net Cash Provided by Operations

Net cash provided by operating activities was \$20.9 million for the six months ended June 30, 2021, compared to \$22.6 million provided by operating activities during the same period in 2020, a decrease of \$1.7 million. The decrease was due to changes in working capital, including payments for income taxes of \$8.4 million partially offset by a reduction in net loss in the six months ended June 30, 2021 against the comparable 2020 period.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 was \$22.7 million, principally due to the acquisition of three NDAs and an ANDA from Sandoz, Inc. for \$20.7 million in consideration and \$1.6 million of capital expenditures during the period. Net cash used in investing activities for the six months ended June 30, 2020 was \$60.4 million, principally due to the January 2020 acquisition of 23 generic products and inventory and materials from Amerigen Pharmaceuticals, Ltd. for \$57.4 million and \$2.3 million of capital expenditures during the period.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$18.2 million for the six months ended June 30, 2021, principally due to borrowings of \$24.0 million on the Revolver, \$5.2 million of maturity payments on the Term Loan and DDTL, and \$0.8 million of treasury stock purchased in relation to restricted stock vests. Net cash provided by financing activities was \$3.1 million for the six months ended June 30, 2020, principally due to net borrowings of \$7.5 million on the Revolver and \$0.4 million of proceeds from stock option exercises, partially offset by \$3.3 million of maturity payments on the Term Loan and DDTL and \$1.5 million of treasury stock purchased in relation to restricted stock vests.

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CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, government rebates, returns, and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

A summary of our significant accounting policies is included in Part II, Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2020. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Part I, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2020.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

A discussion of the recently issued accounting pronouncements is described in Note 1, *Business, Presentation, and Recent Accounting Pronouncements*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q and is incorporated herein by reference.

OFF-BALANCE SHEET ARRANGEMENTS

As of June 30, 2021, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

CONTRACTUAL OBLIGATIONS

As of June 30, 2021, our contractual obligations have not changed materially from the amounts reported in our most recent Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks include interest rate risk, equity risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, interest rate risk, equity risk, and foreign currency exchange rate risk could have a significant impact on our results of operations.

In December 2018, we refinanced our previous \$125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to \$265.2 million. The five-year Credit Facility is comprised of a \$72.2 million term loan (the "Term Loan"), a \$118.0 million delayed draw term loan (the "DDTL") and a \$75.0 million revolving credit facility (the "Revolver"), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. In March 2020, we drew \$15.0 million under the Revolver, of which \$7.5 million was repaid. In April 2021, we drew \$24.0 million under the Revolver. As of June 30, 2021, \$43.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a 1-month LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending on our total leverage ratio. On the Revolver, we incur a commitment fee at a rate

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per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of June 30, 2021, we had a \$205.7 million outstanding balance on the Credit Facility.

In April 2020, we entered into an interest rate swap to manage our exposure to the variable interest rate on our Term Loan and DDTL borrowings. The interest rate swap hedges the variable cash flows associated with interest payments on borrowings under the Term Loan and DDTL, effectively providing a fixed rate of interest throughout the life of these borrowings. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended June 30, 2021 by less than \$1,000.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated transactions from our ANI Pharmaceuticals Canada Inc. subsidiary from the Canadian dollar to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended June 30, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2021. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

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Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2020 under the heading “Part I — Item 1A. Risk Factors.” The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results.

At the June 2021 Annual Meeting of Stockholders, our stockholders approved, in connection with the Company’s pending acquisition of Novitium Pharma LLC (“Novitium”), the issuances of (a) 2,466,667 shares of common stock to certain members of Novitium in connection with the Novitium acquisition, and (b) 25,000 shares of Series A Convertible Preferred Stock to Ampersand 2020 Limited Partnership in connection with its related \$25.0 million PIPE Investment, subject to stockholder approval under Nasdaq Listing Rule 5635(a) (the “Share Issuance Proposal”). The following are new significant risk factors related to the pending Novitium acquisition that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report.

Risks Relating to the Acquisition

Cash expenditures associated with the acquisition of Novitium may create significant liquidity and cash flow risks for us.

We expect to incur significant transaction costs and some integration costs in connection with the acquisition of Novitium. While we have assumed that this level of expense will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the acquisition and integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. To the extent these acquisition and integration expenses are higher than anticipated, we may experience liquidity or cash flow issues.

We will incur substantial debt in order to satisfy our obligations in connection with the acquisition of Novitium.

In order to finance a portion of the purchase price of the Acquisition and expenses associated therewith, we will enter into the New Facility, consisting of a \$300.0 million term loan and a \$40.0 million revolving credit facility. The New Facility will also be used to refinance ANI’s existing senior credit facilities and be secured by substantially all the assets of ANI and its subsidiaries. In order to service the debt we incur under this facility, we will require a significant amount of cash. Our ability to make scheduled payments of principal and interest depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such debt will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition.

Our stockholders will experience dilution as a result of the issuance of shares of our common stock in connection with the acquisition of Novitium and the issuance of our Series A Convertible Preferred Stock in the PIPE Investment.

As of July 15, 2021, we had 12,745,573 shares of common stock outstanding. The amount of dilution our stockholders may experience is dependent on the number of shares of our common stock actually issued or issuable in connection with the acquisition of Novitium and the related PIPE Investment. The maximum number of shares of our common stock that may be issued or issuable in connection with the acquisition of Novitium and the PIPE Investment is 3,203,478 shares, consisting of (a) 2,466,667 shares to be issued to Novitium Members, and (b) up to 736,811 shares issuable to Ampersand on conversion of the Series A Convertible Preferred Stock to be issued to Ampersand in the PIPE Investment, depending on the price of our common stock over a specified period.

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of time. If we issue all 3,203,478 shares authorized to be issued pursuant to the Share Issuance Proposal, the total number of shares of our issued and outstanding common stock will increase by approximately 25% and such newly issued shares will represent approximately 25% of our outstanding voting power prior to the transactions.

Accordingly, if we issue all 3,203,478 shares authorized by the Share Issuance Proposal, the percentage ownership and voting power held by our existing stockholders will be reduced and our stockholders will experience significant dilution.

The market price of our common stock may decline as a result of the acquisition of Novitium and the related PIPE Investment or the issuance of shares of our common stock in connection with the acquisition of Novitium or the PIPE Investment.

We are unable to predict the potential effects of issuing shares of our common stock in connection with the acquisition of Novitium and the PIPE Investment on the trading activity and market price of our common stock. If we issue all 3,203,478 shares authorized to be issued pursuant to the Share Issuance Proposal, the number of shares of our common stock available for public trading would increase substantially once the shares approved to be issued under the Share Issuance Proposal become available for public trading. Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales might occur, could have a material adverse effect on the price of our common stock.

Failure to complete the acquisition of Novitium could materially and adversely affect our results of operations and the market price of our common stock.

Our consummation of the acquisition of Novitium is subject to many contingencies. We cannot assure you that we will be able to successfully consummate the pending acquisition as currently contemplated or at all. Risks related to the failure of the pending acquisition to be consummated include, but are not limited to, the following:

- we would not realize any of the potential benefits of the transaction, which could have a negative effect on our stock price;
- we may experience negative reactions from customers, clients, business partners, lenders, and employees;
- the trading price of our common stock may decline to the extent that the current market price for our stock reflects a market assumption that the Novitium acquisition will be completed; and
- the attention of our management may be diverted to the Acquisition rather than to our own operations and the pursuit of other opportunities that could have been beneficial to us.

The occurrence of any of these events individually or in combination could materially and adversely affect our results of operations and the market price of our common stock.

If the acquisition of Novitium is consummated, the combined company may not perform as we or the market expects, which could have an adverse effect on the price of our common stock.

Even if the Novitium acquisition is consummated, the combined company may not perform as we or the market expects. Risks associated with the combined company following the Acquisition include:

- integrating businesses is a difficult, expensive, and time-consuming process, and the failure to successfully integrate our businesses with the business of Novitium in the expected time frame would adversely affect our financial condition and results of operation;
- the acquisition of Novitium will materially increase the size of our operations, and if we are not able to effectively manage our expanded operations, our common stock price may be adversely affected;
- it is possible that our key employees or key employees of Novitium might decide not to remain with us after the Novitium acquisition is completed, and the loss of such personnel could have a material adverse effect on the financial condition, results of operations, and growth prospects of the combined company;
- the success of the combined company will also depend upon relationships with third parties and Novitium's or our pre-existing customers, which relationships may be affected by customer preferences or

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- public attitudes about the Acquisition. Any adverse changes in these relationships could adversely affect the combined company's business, financial condition, and results of operations; and
- if government agencies or regulatory bodies impose requirements, limitations, costs, divestitures or restrictions on the consummation of the Acquisition, the combined company's ability to realize the anticipated benefits of the Acquisition may be impaired.

The obligations and liabilities of Novitium, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Novitium to us.

Novitium's obligations and liabilities, some of which may not have been disclosed to us or may not be reflected or reserved for in Novitium's historical financial statements, may be greater than we have anticipated. The obligations and liabilities of Novitium could have a material adverse effect on Novitium's business or Novitium's value to us or on our business, financial condition, or results of operations. Under the merger agreement relating to the Novitium acquisition, we have only limited indemnification with respect to obligations or liabilities of Novitium, whether known or unknown. In addition, even in cases where we are able to obtain indemnification, we may discover liabilities greater than the contractual limits or the financial resources of the indemnifying party. In the event that we are responsible for liabilities substantially in excess of any amounts recovered through rights to indemnification or alternative remedies that might be available to us, or any applicable insurance, we could suffer severe consequences that would substantially reduce our earnings and cash flows or otherwise materially and adversely affect our business, financial condition, or results of operations.

If the acquisition of Novitium is consummated, the global nature of Novitium's operations (including those of its Indian subsidiary Novitium Labs Private Limited) will subject us to political and economic risks that could adversely affect our business, results of operations, or financial condition.

The risks presented by global operations include:

- limitations on ownership or participation in local enterprises;
- price controls, exchange controls, and limitations on repatriation of earnings;
- transportation delays and interruptions;
- the application of additional legal, regulatory and taxation regimes to our operations;
- political, social, and economic instability and disruptions in applicable regions;
- acts of terrorism;
- government embargoes or foreign trade restrictions;
- imposition of duties and tariffs and other trade barriers;
- import and export controls;
- labor unrest and current and changing regulatory environments;
- fluctuations in foreign current exchange and interest rates;
- difficulties in staffing and managing multi-national operations;
- limitations on our ability to enforce legal rights and remedies; and
- the severity and duration of the COVID-19 pandemic and its impacts where we operate globally.

If we are unable to successfully manage these and other risks associated with managing the expansion of our business to the jurisdictions in which Novitium operates, including India, the risks could have a material adverse effect on our business, results of operations, or financial condition.

If the acquisition of Novitium is consummated, our expanded international operations would increase our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations.

The Foreign Corrupt Practices Act and other anti-corruption laws and regulations ("Anti-Corruption Laws") prohibit corrupt payments by our employees, vendors, or agents. From time to time, we receive inquiries from

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authorities in the U.S. and elsewhere about our business activities outside of the U.S. and our compliance with Anti-Corruption Laws. While we devote substantial resources to our global compliance programs and have implemented policies, training, and internal controls designed to reduce the risk of corrupt payments, our employees, vendors or agents may violate our policies and if the pending acquisition of Novitium is consummated, our expanded international operations would significantly increase our exposure to potential liability. Our failure to comply with Anti-Corruption Laws could result in significant fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business, and damage to our reputation. Operations outside of the U.S. may be affected by changes in trade production laws, policies, and measures, and other regulatory requirements affecting trade and investment.

If the acquisition of Novitium is consummated, we would also become subject to Indian and other foreign tax regulations. Such regulations may not be clear, not consistently applied and subject to sudden change, particularly with regard to international transfer pricing. Our earnings could be reduced by the uncertain and changing nature of such tax regulations.

Fluctuations in foreign currency exchange and interest rates could adversely affect our results of operations.

Our business is generally conducted in U.S. dollars. However, the costs of operating in India will be subject to the effects of currency exchange fluctuations of the Indian rupee against the U.S. dollar. When the U.S. dollar weakens against the Indian rupee, our operating costs in such currency will increase. This currency risk can be minimized by matching the timing of working capital borrowing needs against operating cost requirements in India. However, fluctuations in the value of the Indian rupee will create greater uncertainty in our revenues and could have a significant adverse effect on our operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table provides information about common stock repurchased by us during the second quarter of fiscal 2021:

(in thousands, except per share data)

<u>Period</u>	<u>Total Number of Shares Purchased⁽¹⁾</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs</u>
April 1 - April 30, 2021	14,643	\$ 32.02	—	\$ —
May 1 - May 31, 2021	—	\$ —	—	\$ —
June 1 - June 30, 2021	—	\$ —	—	\$ —
Total	14,643	\$ 32.02	—	—

⁽¹⁾ Shares purchased during the period were transferred to the Company from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock awards during the period.

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Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits listed in the Index to Exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

INDEX TO EXHIBITS

Exhibit No.	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2021 formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Income; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity; (v) Condensed Consolidated Statements of Cash Flows; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ANI Pharmaceuticals, Inc. (Registrant)

Date: August 6, 2021

By: /s/ Nikhil Lalwani

Nikhil Lalwani
President and
Chief Executive Officer
(principal executive officer)

Date: August 6, 2021

By: /s/ Stephen P. Carey

Stephen P. Carey
Senior Vice President, Finance and
Chief Financial Officer
(principal financial and accounting officer)